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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/524,048 | 06/08/2005 | Michael West | 181-183 | 6789 |

23117 7590 04/18/2007
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| EXAMINER | |
|---|---|
| OLSON, ERIC | |
| ART UNIT | PAPER NUMBER |
| 1623 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 04/18/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/524,048 | WEST ET AL. | |
| | Examiner | Art Unit | |
| | Eric S. Olson | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *February 8, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## Detailed Action

This application is a national stage application of PCT/AU03/01008, filed August 8, 2003, that claims priority to foreign application AU2002950657, filed August 8, 2002. Claims 1-27 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted February 8, 2005 is acknowledged wherein claim 5 is amended and the specification is amended to indicate continuity.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-27 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The claims are directed to a class of compounds without indicating any practical utility possessed by these compounds. Although the specification hints that they could be used as a library for performing high-throughput screens for drug discovery, there is no reason to believe that any of the compounds actually have utility as drugs. Furthermore, the asserted utility is very vague, as the specification does not provide any details of what biological activities the claimed compounds are suspected of having, or what sort of screens one would be expected to perform on them. Therefore the claimed invention lacks utility.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The aforementioned claims are drawn to compounds which "comprise as a precursor" a particular monosaccharide. It is not clear what is meant by "comprises as a precursor" in this context. There are many different chemical transformations known in the art by which one saccharide can be transformed into another. One skilled in the art would not recognize a specific, definite set of compounds having any one of these monosaccharides as a precursor, but would rather recognize that there exist a variety of different compounds that may or may not

have these compounds as precursors depending on the definition of precursor used. Thus these claims are indefinite.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The base claim 1 recites various functional groups R that in certain embodiments can be heteroalkyl, heteroaryl, or heteroarylalkyl, and that can be optionally substituted. Furthermore the same claim is drawn to "a derivative of a furanose or pyranose form of a monosaccharide." Neither the claims nor the specification give any clear, limiting definition of what heteroatoms or substituents are included within the scope of the claims, or what compounds are contemplated as being derivatives of a monosaccharide. Therefore the claims are indefinite.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Christ et al. (US patent 6184366, cited in PTO-1449) Christ et al. discloses various compounds falling within the limits of instant claims 1, 2, and 4. For example, the compound at the top of columns 15-16 is a compound of claim 1 wherein R1 = O-propylene, R2 = $NH(CO)CH_2(CO)C_{15}H_{31}$, R3 = $O\text{-}C_{10}H_{21}$, R4 = OH, R5 = C5 cyclic heteroalkyl. Additional compounds falling within the claimed structure are found on column 28, lines 45-55 and column 32, lines 20-40, for example. Therefore Christ et al. anticipates the claimed invention.

Claims 1, 3, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Lin et al. (PCT international publication WO02/085867, Reference included with PTO-892) Lin et al. discloses a class of compounds pictured on p. 2, lines 1-5. These compounds fall within the limits of figure I of instant claim 1 wherein n = 0, R = substituted O-alkyl, R2 = methoxy, R3 = OH, and R5 = NHZ. In particular, the methyl group at R2 meets the limitations of Y1 in instant claim 26. Furthermore, the generic structure on p. 2 of Lin et al. discloses that the amino group (R1 in Lin et al.) can be functionalized with (C=O)alkyl, (C=O)NH-Alkyl, and (C=O)NH-Aryl groups that include the specific groups recited in instant claim 27. Thus the claimed invention is anticipated by Lin et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (PCT international publication WO02/085867, Reference included with PTO-892) The disclosure of Lin et al. is discussed above. Lin et al. does not explicitly exemplify the specific substituents recited in instant claim 27.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the specific embodiments of the invention of Lin et al. in which NHZ is, for example, Z1, Z6, Z10, Z18, Z19, or Z26, or various other embodiments of instant claims 27. One of ordinary skill in the art would have been motivated to produce these compounds because they were within the broad teaching of Lin et al. One of ordinary skill in the art would reasonably have expected success because attaching a variety of acyl groups to the affected nitrogen is a simple and routine synthetic transformation easily and routinely preformed by one of ordinary skill in the art. (for example, see scheme 6 on p. 16 of Lin et al.)

Thus the invention taken as a whole is *prima facie* obvious.

Claims 1, 2, 4, and 22-26 are rejected under 35 U.S.C. 103(a) as being anticipated by Hanessian et al. (Reference included with PTO-1449) in view of Carey et

al. (Reference included with PTO-892) Hanessian et al. discloses solid-supported carbohydrates that fall within the limits of the claimed invention of formula I wherein R1 – methoxy, R2 = NHCbz, R3 = OH, and R4 and R5 are linked by a benzylidine acetal to a benzaldehyde-functionalized Wang resin, which is a functionalized polystyrene resin. (p. 103, Scheme 2, Compounds B and C) Hanessian et al. does not disclose a compound having a N(Y)Z group that is not recited in the exclusionary proviso of instant claim 1, found on p. 5 of the claims.

Carey et al. discloses that various other protecting groups besides Cbz may be used to protect amines during synthesis. (pp. 831-835) For example, the allyl carbamate, nitrobenzyl carbamate, trifluoroethyl carbamate, pentenoyl, and phenylsulfonamide protecting groups can all be used to protect amines.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the compound of Hanessian et al. with any of the other protecting groups mentioned by Carey et al. in place of Cbz. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Carey et al. discloses that these protecting groups are useful for protecting amines during synthesis. One of ordinary skill in the art would have reasonably expected success because the recited protecting groups are well known in the art and utilizing them in a synthesis is well within the ordinary and routine level of skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

Claims 1, 2, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukase at al. (Reference included with PTO-1449) Fukase et al. discloses two compounds (labeled **14** and **3** on p. 1695, scheme 3) that fall within the limitations of instant claim 1. In particular, they fall within formula I of claim 1 when R1 = O-allyl, R2 = NH-Fmoc, R3 = OH, and either R4 = substituted benzyloxy or R4 and R5 are together protected by a nitrobenzylidene group. However, Fukase et al. does not disclose a compound having a N(Y)Z group that is not recited in the exclusionary proviso of instant claim 1, found on p. 5 of the claims.

Carey et al. discloses that various other protecting groups besides Cbz may be used to protect amines during synthesis. (pp. 831-835) For example, the allyl carbamate, nitrobenzyl carbamate, trifluoroethyl carbamate, pentenoyl, and phenylsulfonamide protecting groups can all be used to protect amines.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the compound of Fukase et al. with any of the other protecting groups mentioned by Carey et al. in place of Fmoc. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Carey et al. discloses that these protecting groups are useful for protecting amines during synthesis. One of ordinary skill in the art would have reasonably expected success because the recited protecting groups are well known in the art and utilizing them in a synthesis is well within the ordinary and routine level of skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/491070. (US patent publication 20030232766, Reference cited in PTO-892, herein referred to as '070) Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of '070 substantially overlaps the claimed invention. In particular, when R4 and R5 of claim 1 of '070 are a benzylidene acetal, R3 is hydrogen, R1 = acyl, and R = O-Y, the resulting compound falls within the limits of the claimed invention. Therefore the claimed invention is anticipated by claim 1 of '070.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Conclusion**

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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